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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

1016760061P

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on \_\_\_\_\_

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Application Number

10/633,254

Filed

August 1, 2003

First Named Inventor

Douglas G. Evans

Art Unit

3773

Examiner

Julian W. Woo

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

/Todd W. Wight/

Signature

assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

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Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

October 20, 2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.



\*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Douglas G. Evans, et al.

Application No.: 10/633,254

Confirmation No.: 4792

Filed: August 1, 2003

Art Unit: 3773

For: **SELF-ANCHORING SLING AND  
INTRODUCER SYSTEM**

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Examiner: Julian W. Woo

**ARGUMENTS FOR PRE-APPEAL BRIEF PANEL REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

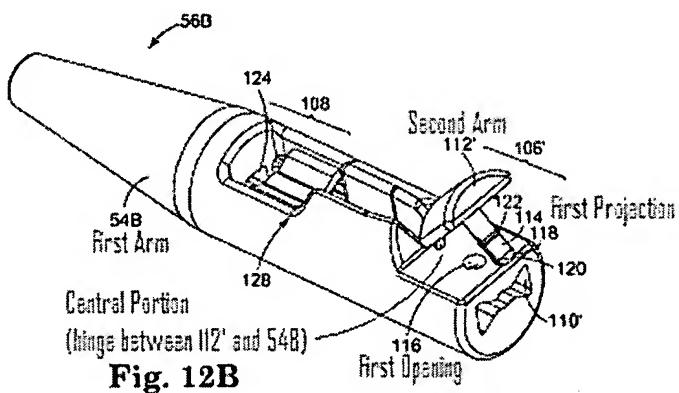
Applicant respectfully submits the following arguments in support of the Pre-Appeal Brief Request for Review filed concurrently herewith.

In a final Office Action mailed June 18, 2008 (hereinafter, "Office Action"), independent claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over USPN 6,612,977 to Staskin (hereinafter, "Staskin") in view of USPN 4,509,516 to Richmond (hereinafter, "Richmond"). Dependent claims 35 and 36, the subject matter of which was presented in new independent claim 132, were rejected under 35 U.S.C. § 102(e) as anticipated by Staskin. In an Advisory Action, dated August 26, 2008, the Office maintained the rejection of independent claim 1 under 35 U.S.C. § 103 over Staskin in view of Richmond, and indicated that new claim 132 would also be rejected under 35 U.S.C. § 103 over Staskin in view of Richmond.

Applicants believe that the Office has failed to present a *prima facie* case of obviousness, and respectfully request reconsideration of the outstanding rejections in view of the arguments presented herein.

Independent claim 1 recites, *inter alia*, “a first arm pivotally mounted to the central portion and having a first opening at a first end; and a second arm pivotally mounted to the central portion” (underlining added for emphasis).

Applicants argued that in view of the drawing and description of Staskin, it was clear that the surface through which the opening 116 extends is *fixed*, as opposed to being *pivotally mounted* as recited in independent claim 1. The Office responded in the Advisory Action that “Staskin indeed discloses a first arm (112') pivotally mounted to a central portion having first opening 116, or vice versa. That is, the hinge between 112' and 54b allows relative pivotal motion between 112' and the central portion, such that 112' can also be ‘fixed,’ while the central portion pivots relative to the first arm.” An annotated version of FIG. 12B of Staskin is provided below, including the features alleged by the Office Action to support a rejection of independent claim 1.



Initially, Applicants note that there is no description or showing of a hinge, contrary to the allegation in the Office Action. As shown above, FIG. 12B of Staskin merely shows a “snap-like element 112” without disclosing any pivotal relationship. Staskin, col. 20:9. In fact, it is more likely that the alleged second arm 112' is connected via an arm piece and a hole as opposed to a straight hinge as alleged. This is because a straight hinge would not permit the projection 114 to move fully into the opening 116 as one skilled in the art would recognize. Staskin does not describe the relationship of the element 112' with respect to the rest of the dilator. Accordingly, Staskin does not appear to be enabled for the purposes of showing a pivotal mounting as claimed.

However, assuming *arguendo* that Staskin does show a pivotal mounting in FIG. 12B, there is no showing of at least either: 1) a first arm pivotally mounted to a *central portion*, or 2) a first arm pivotally mounted to a central portion *and* a second arm pivotally mounted to a central portion. According to the interpretation by the Office, the alleged hinge between 54B and 112' is the central portion, the first arm is 54B, and the second arm is 112'. However, if the alleged hinge is the central portion, then the claimed feature of the first arm being "pivotally mounted" to the central portion is not shown as the first arm cannot be pivotally mounted to the alleged hinge. That is, there must be some intervening stationary piece between the arm and the pivot point. Moreover, even assuming *arguendo* that FIG. 12B shows a first arm pivotally mounted to a central portion, it is unmistakable that FIG. 12B does not also show a second arm pivotally mounted to a central portion as claimed. That is, the claimed invention requires at least two separate pivot points, one between the first arm and the central portion, and another between the second arm and the central portion. This requirement cannot be shown by the alleged hinge of Staskin. Richmond fails to supply these features missing from Staskin.

Independent claim 132 recites, *inter alia*, "an integrally formed introducer needle including an elongated shaft connecting first and second flat spatulated sections. . . the shaft including a straight portion connected to a curved portion. . . and a handle including. . . an elastically-biased latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section inserted into the distal end opening of the housing to secure the handle to the introducer needle" (underlining added for emphasis).

According to the Office in view of the comments in the Advisory Action, Staskin shows the features of claim 1 other than the constant width portion having an opening therethrough at least in FIGS. 1, 1A, 4, 12A, 12B, 16A-16D, and 18A-18E. In particular, the Office notes that the claimed introducer needle is shown by Staskin component 60A or 60B and the claimed handle is shown by Staskin component 64G.

With respect to the claimed introducer needle, Applicants submit that Staskin fails to show or describe at least a straight portion connected to a curved portion. In particular, claim 132

requires that the needle includes a shaft connecting first and second flat spatulated sections, and that the shaft includes a straight portion connected to a curved portion. The Advisory Action does not identify which part of the Staskin component 60A is the claimed straight portion. Thus, if portion 126 is the claimed flat spatulated portion, as alleged, then portion 130 cannot be the claimed straight portion as alleged in the Final Office Action, because it is not part of the shaft which is recited as *connecting* the first and second flat spatulated sections. In the same way, if the tapered portion of portion 170 is the claimed flared section, as alleged, then the portion distal of the flared portion cannot be the claimed straight portion. Further, nowhere does Staskin disclose a shaft with both straight and curved sections, instead stating the preference for a uniformly *curved* needle as follows:

In a preferred embodiment, the needle 60 may be substantially symmetric about a centerpoint, that is, the radius of curvature of the needle 60 may be substantially constant and either a handle or a dilator may be attached to either end of the needle 60.

(Staskin, col. 23:54-58).

Accordingly, Staskin does not show or describe at least a shaft including a straight portion connected to a curved portion. Richmond fails to show or describe this feature missing from Staskin.

With respect to the claimed handle, Applicants submit that Staskin fails to show or describe at least an elastically-biased latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section. In particular, the Advisory Action identifies element 198 of alleged handle 64G as an elastically-biased latch portion having a projection (see FIGS. 18A-B of Staskin). However, the cross-sectional view of FIG. 18B shows that “push button assembly 198 comprises a button or knob-shaped component 202 that attaches to a yoke 204.” Staskin, col. 25:7-9. “In particular, the yoke 204 is attached to the button 202 via snap tongs 206 that lock the button 202 and yoke 204 together.” Staskin, col. 25:10-12. Thus, contrary to the assertion by the Office, there is no feature associated with element 198 that could constitute a “projection dimensioned and disposed in the housing to engage the flat spatulated section inserted into the distal end opening of the housing to secure the handle to the introducer needle,” as claimed.

The only projections shown in Staskin with respect to the push button assembly 198 are the tongs 206, which lock the button to the yoke, rather than engage a flat spatulated section, as claimed.

Accordingly, Staskin does not show or describe at least an elastically-biased latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section. Richmond fails to supply this feature missing from Staskin, as the disclosed handle includes co-operating threaded portions, rather than a elastically-biased latch portion. *See, e.g.*, Richmond FIGS. 1-3.

In view of the above, the asserted combination of Staskin/Richmond fails to establish a *prima facie* case of obviousness with respect to independent claims 1 and 132 at least because not all of the claim elements are shown or described by the cited combination. With respect to dependent claims 2-4 and 120-131, without conceding the propriety of the asserted combinations, Applicants submit that each depends from patentable independent claim 1 and is therefore patentable.

For the convenience of the panel, the Applicants' positions are presented here in summary form. A more developed discussion of the traversal of the rejection of the pending claims under 35 U.S.C. § 103(a) as obvious over Staskin in view of Richmond are a matter of record in the prosecution history and can be found in the Response filed August 12, 2008.

Dated: October 20, 2008

Respectfully submitted,

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